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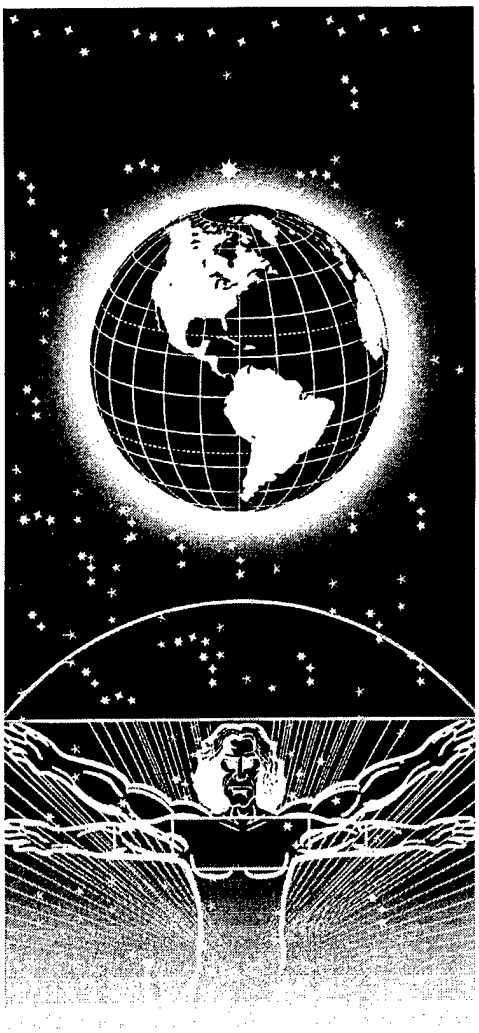

UNITED STATES AIR FORCE RESEARCH LABORATORY

TESTING AND EVALUATION OF THE INTERNATIONAL BIOMEDICAL, INC., MODEL 20M, NEONATAL TRANSPORT SYSTEM

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February 2000

NOTICES

This final technical report was submitted by personnel of the Protection Systems Branch, Biodynamics and Protection Division, Human Effectiveness Directorate, Air Force Research Laboratory, AFMC, Brooks Air Force Base, Texas, under job order 7184-56-01.

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REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. AGENCY USE ONLY (Leave blank)	2. REPORT DATE	3. REPORT TYPE AND DATES COVERED
	February 2000	Final, October 1999

4. TITLE AND SUBTITLE

Testing and Evaluation of the International Biomedical, Inc., Model 20M, Neonatal Transport System.

5.FUNDING NUMBERS

PE: 62202F
PR: 7184
TA: 56
WU: 01

6. AUTHOR(S)

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7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

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8. PERFORMING ORGANIZATION REPORT NUMBER

AFRL-HE-BR-TR-2000-0029

9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES)

10. SPONSORING/MONITORING AGENCY REPORT NUMBER

11. SUPPLEMENTARY NOTES

12a. DISTRIBUTION/AVAILABILITY STATEMENT

Approved for public release; distribution unlimited.

12b. DISTRIBUTION CODE

13. ABSTRACT (Maximum 200 words)

The International Biomedical, Inc., Model 20M, Neonatal Transport System is an infant transport incubator. It provides an environment to support an infant's requirements while being transported. The Neonatal Transport System has a standard infant chamber that circulates warmed air and comes equipped with one main door, one head door, and two hand ports. The Neonatal Transport Systems main door allows access for infant placement inside the infant chamber as well as further access for medical care. To prevent excessive heat loss, the main door has hand ports to allow infant care without opening the main door. The Neonatal Transport System has an accessory module containing a Protocol vital signs monitor, a International Bio-Med MVP-10 ventilator, a Mine Safety Appliance oxygen analyzer, a Impact continuous/intermittent suction device, and intravenous infusions using up to four Baxter syringe pumps. The Neonatal Transport System provides medical grade oxygen and air using internal "Q" size tanks and/or external gas sources. The unit operates off of 115 VAC/60 and 400 Hz and internal rechargeable battery. The unit weighs approximately 123.76 lbs. Its dimensions are 37.5 in. W. X 43.0 in. H. X 21.88 in. D.

14. SUBJECT TERMS

Neonatal	incubator	infant
NTS	aeromedical	warmer
Airworthy	aircraft	

15. NUMBER OF PAGES

29

16. PRICE CODE

17. SECURITY CLASSIFICATION OF REPORT	18. SECURITY CLASSIFICATION OF THIS PAGE	19. SECURITY CLASSIFICATION OF ABSTRACT	20. LIMITATION OF ABSTRACT
Unclassified	Unclassified	Unclassified	UL

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ACKNOWLEDGMENTS

The author would like to thank those who helped and provided advice during the evaluation of International Biomedical, Inc., Model 20M Neonatal Transport System. The author would especially like to thank the following people:

Major James Sylvester	Program Manager
2Lt Jonathan Raker	Biomedical Engineer
MSgt Pamela Forest	Medical Service Journeyman
MSgt Allen Jones	Aeromedical Research Technician
Mr. Edward Hade	Electronics Engineer
Mr. Victor Elizondo	Electronics Technician

TESTING AND EVALUATION OF THE INTERNATIONAL BIOMEDICAL, INC., MODEL 20M, NEONATAL TRANSPORT SYSTEM

BACKGROUND

Air Mobility Command requested the Air Force Medical Equipment Development Laboratory (AFMEDL) participation in evaluating and approving International Biomedical, Inc., Model 20M Neonatal Transport System for use on board USAF aeromedical evacuation aircraft. Specific components of the International Biomedical, Inc., Model 20M Neonatal Transport System that underwent evaluation included: the International Biomedical, Inc., Model 20M basic unit: (S/N: 889); the Baxter, Inc., Syringe Pump Model AS50 (S/N's: 8120149AB, 8120231AB, 8120236AB, 8120256AB); the Mine Safety Appliance, Inc., Oxygen Analyzer Model Miniox 3000 (S/N: B765J98, P/N: 814365); the Impact, Inc., Continuous/Intermittent suction pump, Model 326/326M (S/N: 9904006); the Impact, Inc., Continuous/Intermittent suction pump, Model 326/326M power supply (S/N: 9904006); the International Biomedical, Inc., Air and Oxygen Blender (S/N: KKF01321, P/N: 10065); the Timeter Instruments, Corp., Oxygen Flowmeter, Model Classic 0-16; International Bio-Med, Inc., Pediatric Respirator Model MVP-10 (S/N: 1051941); Protocol Systems, Inc., Propaq, Model 206EL (S/N: EC001317) with power supply (S/N: Not Available); and the International Biomedical, Inc., Retractable Bar Fastner System (P/N: 3170686) for securing the NTS in Air Force ambulances. All components of the model 20M were tested for airworthiness. Throughout this report, the term Equipment Under Test (EUT) refers to the model 20M and all internal and external components.

DESCRIPTION

The EUT is an infant transport incubator. It provides an environment to support an infant's requirements while being transported. The EUT's standard infant chamber circulates warmed air and comes equipped with one main door, one head door, and two hand ports. The EUT's main door allows access for infant placement inside the infant chamber as well as further access for medical care. To prevent excessive heat loss, the main door has hand ports to allow infant care without opening the main door. The EUT has an accessory module containing a Protocol vital signs monitor, a International Bio-Med MVP-10 ventilator, a Mine Safety Appliance oxygen analyzer, a Impact continuous/intermittent suction device, and intravenous infusions using up to four Baxter syringe pumps. The EUT provides medical grade oxygen and air using internal "Q" size tanks and/or external gas sources. The unit operates off of 115 VAC/60 and 400 Hz and internal rechargeable battery. The unit weighs approximately 123.76 lbs. Its dimensions are 37.5 in. W. X 43.0 in. H. X 21.88 in. D.

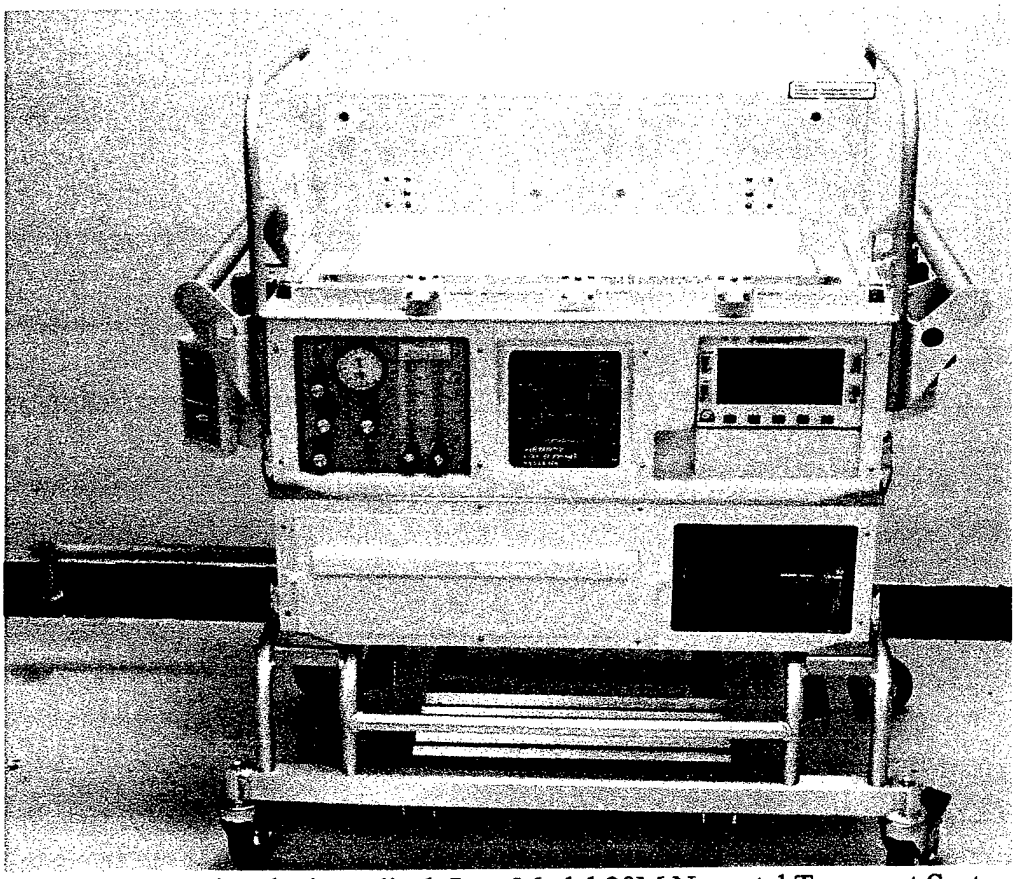

Figure 1. International Biomedical, Inc., Model 20M Neonatal Transport System

PROCEDURES

Test methods and performance criteria were derived from nationally recognized performance guidelines (1 & 2), military standards (3-8), and manufacturer's literature (9). The AFMEDL Procedures Guide describes additional safety and human interface issues to be considered during equipment testing (10). A test setup and performance check was developed specific to this EUT to verify its proper functioning under various testing conditions. All tests were conducted by AFMEDL personnel assigned to the Systems Research Branch, Biodynamics and Protection Division, Human Effectiveness Directorate, Air Force Research Laboratory, Brooks AFB, Texas unless otherwise noted.

The EUT was subjected to various laboratory and in-flight tests to observe and evaluate its performance under anticipated operational conditions.

1. Initial Inspection

2. Vibration

3. Electromagnetic Interference (EMI)

4. Thermal/ Humidity Environmental Conditions, encompassing:

    a. Hot Operation

    b. Cold Operation

    c. Humidity Operation

    d. Hot Temperature Storage

    e. Cold Temperature Storage

5. Hypobaric Conditions

    a. Cabin Pressure/Altitude

    b. Rapid Decompression to simulated flight level

6. Airborne Performance

INITIAL INSPECTION AND TEST PREPARATION

a. The EUT was inspected for quality of workmanship, production techniques and pre-existing damage.

b. The EUT was checked to ensure it met safety requirements and operating characteristics established in National Fire Protection Agency (NFPA) 99 (1); AFI 41-203, Electrical Shock Hazards (3); AFI 41-201, Equipment Management in Hospitals (4). Ground resistance and leakage current measurements were made at 115 VAC/60 Hz and 115 VAC/400 Hz.

c. The EUT was examined to ensure it met basic requirements for human factor design as outlined in MIL-STD 1472 (5).

d. A test setup and performance check was developed to evaluate the EUT's operation in accordance with manufacturer/customer specifications throughout the various testing conditions.

TEST SETUP

Test Setup: The nine individual devices that make up the NTS were evaluated together as a system. A series of simulated signals was applied to each device with the resulting performance measured while the NTS was exposed to the stresses of flight. Some devices have been recently tested and certified for flight by AFMEDL. In these cases, prior test results were

reviewed and accepted as providing satisfactory demonstration of airborne performance. Individual device descriptions and performance checks are outlined below:

Infant Incubator Model 20M: The function of the incubator is to provide a warm environment, adequate ventilation for fresh air exchange, and delivery of external supplemental oxygen (flowmeter or ventilator). Test methods used were similar to those used in previous AFMEDL Model 185 and 20H Transport Incubator evaluations (see USAFSAM-TR-90-23). Three temperature probes/sensors measured the incubator's infant chamber temperature characteristics.

Performance Check: The incubator was pre-warmed to 37°C using 110 VAC/60 Hz power under standard ambient conditions. The incubator's infant chamber temperature was measured and recorded throughout each test.

The NTS Skin Temperature Probe is plugged into a receptacle located on the NTS control panel. It is normally attached to the infant's skin. This thermistor displays the infant's skin temperature by depressing the "Skin Temp" button on the NTS control panel. A commercial heating pad was used to substitute as a heat source during testing.

Performance Check: The following Performance Check was used to validate the function of the NTS Skin Temperature Probe during vibration and environmental testing. Measurements taken during initial operation at standard ambient conditions served as a baseline for later comparison. The performance check for the NTS Skin Temperature Probe is defined below.

Procedure:

1. Plug temperature probe into "Skin Temp" receptacle on NTS control panel.
2. Attach skin probe and second source thermistor to commercial heating pad.
3. Plug NTS and commercial heating pad into 115 VAC/60 Hz power.
4. Turn on NTS, second source thermistor, and commercial heating pad.
5. Place commercial heating pad into infant chamber on NTS and allow NTS temperature to stabilize.
6. Adjust commercial heating pad to low setting and allow temperature to stabilize.
7. Record temperature data from skin probe and second source thermistor.

Bio-Med, Model MVP-10 Pediatric Respirator: This device has been previously evaluated by AFMEDL. The device was tested and approved for aerovac as a stand-alone device (May 87) and as a part of the previously aerovac approved NTS (Dec 90). Preformance measurements were only taken during these current efforts during vibration and environmental operational testing.

Performance Check: The following performance check was used to validate the function of the Bio-Med, Model MVP-10 Pediatric Respirator in each test condition. Measurements taken during initial operation at standard ambient conditions served as a baseline for later comparison.

Procedure:

1. Connect the patient breathing circuit from the respirator to a Michigan Instruments, Ventilator Analyzer infant input port.
2. Insert an RP200 resistor inline with the patient breathing circuit at the mask connection to the analyzer.
3. Ventilate the test lung analyzer at the following settings:

-Mode:	Cycled
-Inspiratory Time:	1.33
-Expiratory Time:	2.67
-Airway Pressure:	28 cmH_2O
-Flow:	4 lpm
-PEEP/CPAP:	Off
-FiO_2:	30%
-Breath Rate:	30-60

4. Record data using PneuView (software supplied with the Michigan Analyzer and installed on a laptop computer).

Protocol Propaq, Model 206EL Neonatal Monitor: This device has been previously tested and approved for aerovac (August 97) by AFMEDL. Measurements were only taken during vibration and operational environmental testing.

Performance Check: The following performance check was used to validate the function of the Propaq 206EL Physiological Monitor in each of the test conditions. Measurements taken during initial operation at standard ambient conditions served as a baseline for later comparison.

Procedure:

1. Plug the 3-lead ECG cable into the ECG port on the 206EL
2. Attach the 3 ECG leads to the corresponding color-coded receptacles on a Bio-Tek Multiparameter Simulator (LionHeart 3C).
3. Secure the non-invasive blood pressure (NIBP) tubing line to the NIBP port on the 206EL and the "Pressure Port" on a Bio-Tek BP Pump tester. Configure the NIBP tester with the following settings:

   Mode = Infant Settings, "Standard set of pressures #1"
   Systolic = 46 – 92
   Diastolic = 38 – 71
   Mean = TBD
   Heart Rate = 120 – 160

4. Plug the SpO_2 cord into its corresponding SpO_2 port on the 206EL. Attach the SpO_2 sensor to the "finger" probe on a Bio-Tek SpO_2 simulator. Set the simulator to monitor for Nellcor pulse oximeters; 98% and 160 bpm.
5. Plug the CO_2 sensor cord into its corresponding port on the 206EL's CO_2 module. Attach an

airway adapter and sensor to the CO_2 line. CO_2 module will be hanging and open to ambient conditions. Display should read "Srch" and no alarm presents. Configure the Propaq 206EL monitor ECG lead II and display temperature in °C. The Propaq 206EL will continuously monitor temperature, P1, SpO_2, and CO_2. Program NIBP operation for automatic at one-minute intervals.

Bird, Model 3800A Air-Oxygen Blender: This device blends compressed air and medical grade oxygen for delivery to a ventilator at 50 psi (+/-5); at percentages determined by the blender control knob; from 21 to 100%. The Bird, Model 3800A is also equipped with an auxiliary outlet for attaching an oxygen flow meter. This device has been previously tested by AFMEDL. This device was tested as a part of the previous NTS model (published Dec 90) therefore, no measurements were taken during this NTS evaluation.

Impact Corp., Model 326M, Suction Unit: This device was tested by itself and approved for aerovac (Jan 97) therefore, measurements were only taken during vibration and environmental testing.

Performance Check: The following performance check was used to validate the function of the Impact 326M Suction Unit in each of the test conditions. Measurements taken during initial operation at standard ambient conditions served as a baseline for later comparison. The performance check for the Impact 326M is defined below.

Procedure(s): The performance check for the Impact 326M consists of four separate tests. These tests are outlined below (1-4).

1. Time to reach 300 mmHg – Attach collection canister with collection tubing to unit, turn unit on, set vacuum adjust to maximum. Occlude tubing and using a stopwatch measure how long unit takes to reach 300 mmHg. Repeat test 3 times and record results. Next, connect a flowmeter in the vacuum line to measure free airflow. Turn unit on and record results. NOTE: Unit must provide a vacuum level of 300 mmHg in four (4) seconds (or less) at 25 lpm free flow.

2. Maximum Vacuum Level – Attach collection canister with collection tubing to unit, select continuous mode, occlude collection tubing, set vacuum adjust to maximum, turn unit on and record results.

3. Vacuum Gauge Accuracy – Attach collection canister with collection tubing to unit, connect a calibrated vacuum gauge to collection tubing, select continuous mode, turn unit on, assess unit's gauge by setting vacuum adjust on unit to read 100, 150, 250, 500 mmHg, and record results. NOTE: This test was performed one time during initial/baseline testing. However, a calibrated Universal Biometer, Model DPM-III was inline with the collection canister during all phases of AFMEDL testing and used for gauge comparison.

4. Intermittent Operation – Attach collection canister with collection tubing to unit, select intermittent mode, set on/off times for 10 seconds each, vacuum adjust to maximum. Turn

unit on and ensure vacuum levels do not exceed 235 mmHg. Record "on" and "off" cycle times with a stopwatch for accuracy.

Mine Safety Appliances company (MSA), Model Mini-Ox 3000, Oxygen Monitor: This device was tested and approved for aerovac (January 98) therefore, measurements were only taken during vibration and operational environmental testing.

Performance Check: Connect the coiled cable to receptacle on the right side of the 3000 and the other end to the oxygen sensor. Turn 3000 on. Once CAL screen is visible press 21% button. Next press the unlock button. Calibration sequence will start. Upon termination of the 21% calibration cycle, attach a tee adapter (supplied with the 3000) to the oxygen sensor and run a steady flow of oxygen through it. Press the 100% button, then the unlock button. The 100% calibration sequence will now start. Once the calibration sequence is complete the 3000 is ready to read and display the percentage of oxygen flowing past the oxygen sensor.

The Baxter, Inc., Model AS50, Syringe Pump: This device was tested and approved for aerovac (September 98) therefore, measurements were only taken during vibration and operational environmental testing. The NTS model 20M is configured with four AS50 pumps.

Performance Check: The following performance check was used to validate the function of the AS50 during vibration and environmental testing. Measurements taken during initial operation at standard ambient conditions served as a baseline for later comparison. The performance check for the AS50 is as defined below.

Procedure:

1. Fill 60 ml B-D syringe with 60 mls normal saline solution and place in the AS50 pump IAW operator's manual. Program the unit for the following continuous infusion mode settings: Step 1: Select Continuous Infusion Mode (ml/hr or ml/min), Syringe manufacturer = B-D, and syringe size = 60 ml. Step 2: Infusion rate = 12 ml/hr. Step 3: Volume limit = 50 ml.

2. Bio-Tek, Model IDA-4, Infusion Device Analyzer: Purge analyzer IAW manufacturer literature. Connect tubing between syringe (in pump) and Analyzer (Channel A or B). Press "Start" button. While conducting the test, ensure that there are no bubbles present in the line. Purging may be required from time to time.

"Q" Size Gas Cylinders: These cylinders were supplied by International Biomedical, Inc., for the NTS. The supplied cylinders were tested and approved by the Department of Transportation. Cylinders have been flown on previously tested NTS models with no problems encountered to date.

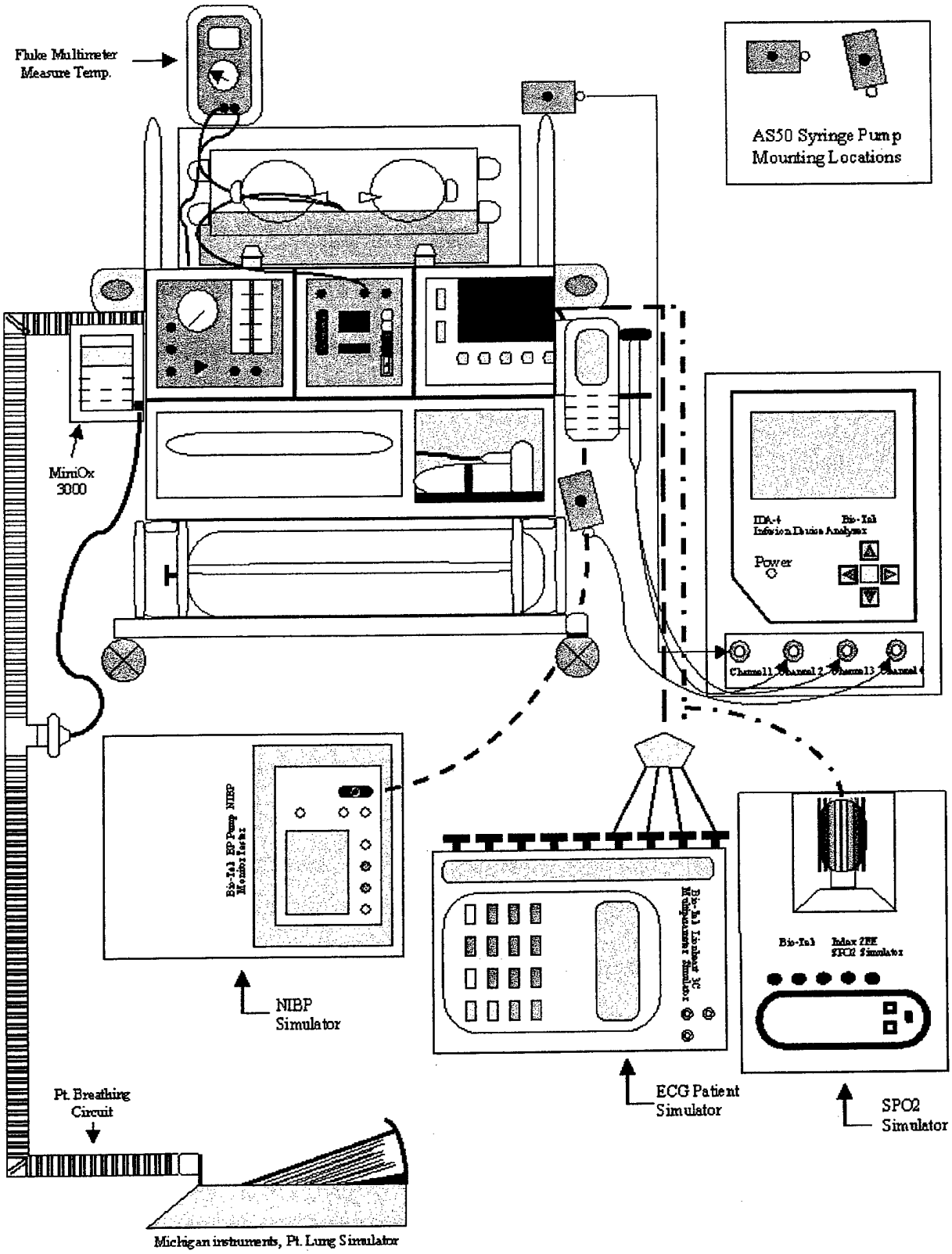

Figure 2. Test Setup

PERFORMANCE CHECK

The above individual performance checks were used to validate the function of the NTS in each of the test conditions. Measurements taken during initial operation at standard ambient conditions served as a baseline for later comparison. The performance check for the NTS is as defined above and will be referenced throughout the Test Condition section. Battery operation performance was assessed against manufacturer claims as outlined in the International Biomedical, Inc., Operator's & Service Manual (9)

VIBRATION

Vibration testing is critical to determine, "the resistance of equipment to vibrational stresses expected in its shipment and application environments" (6). Testing was conducted on a Unholtz-Dickey Corporation Vibration Test System, amplifier model SA30 and shaker model R16W. This testing involved a set of operational tests performed along each of three axes - X, Y, and Z. The EUT was secured to the vibration table using two 5,000 lbs., cargo tie-down straps and four "D" rings. The EUT was subjected to vibration curves with similar intensities and durations as those derived from MIL-STD-810E, Category 10, Figures 514.4-16 and 514.4-17 (Figures 4, 5 and 6).

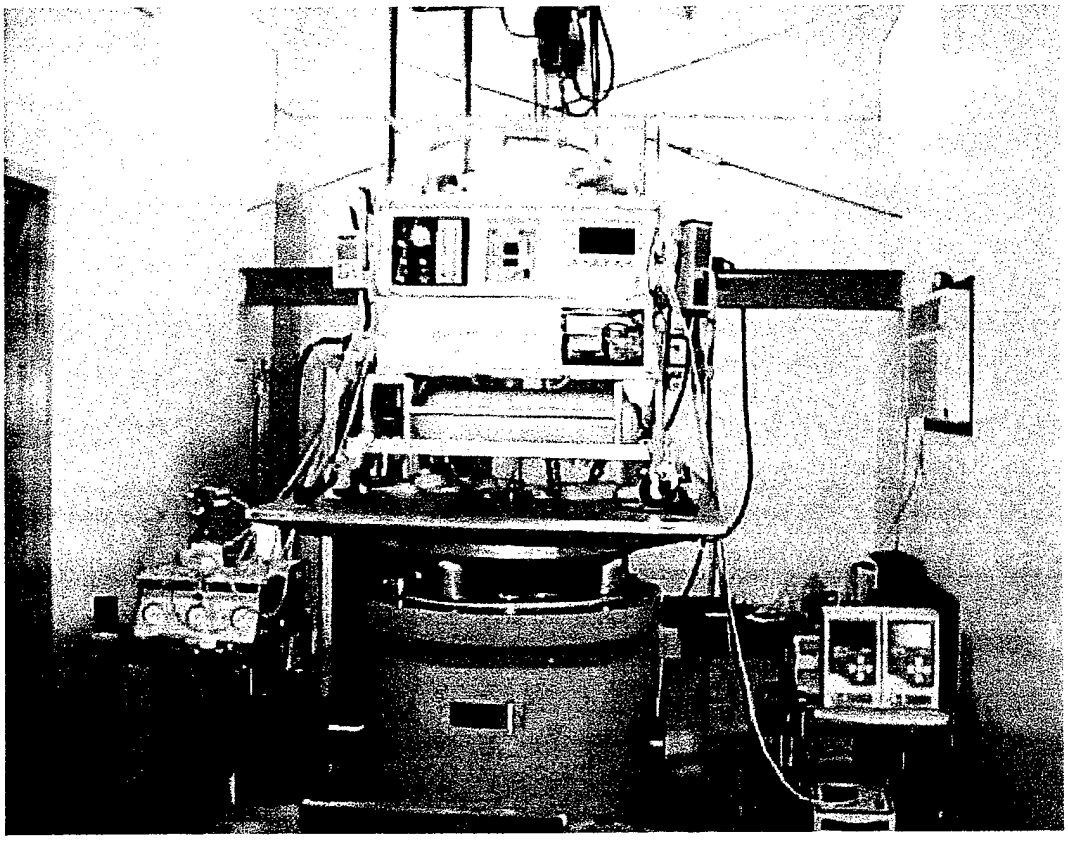

Figure 3. Vibration Table Mounting

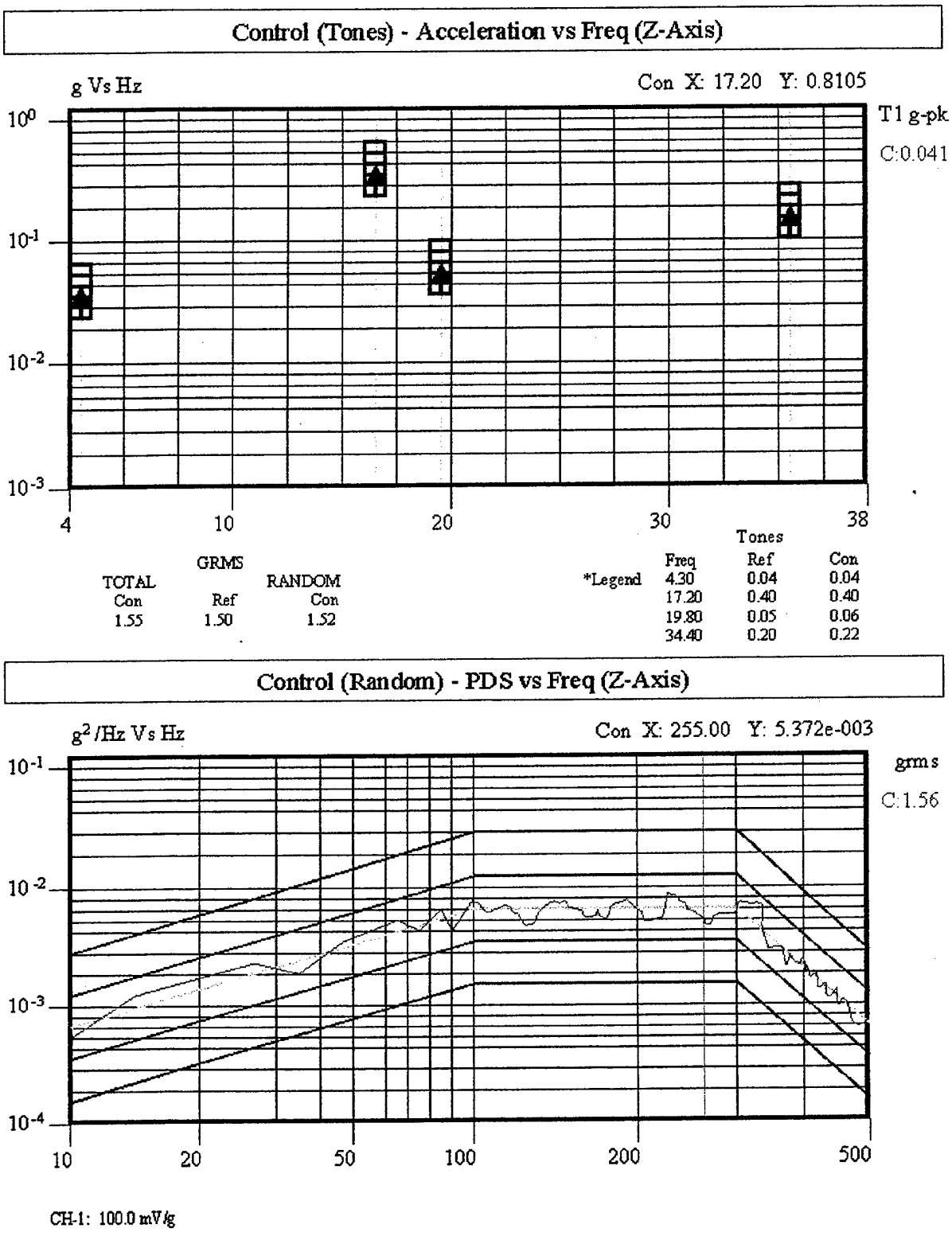

Figure 4. Sine-On-Random Z-Axis based on MIL-STD-810E

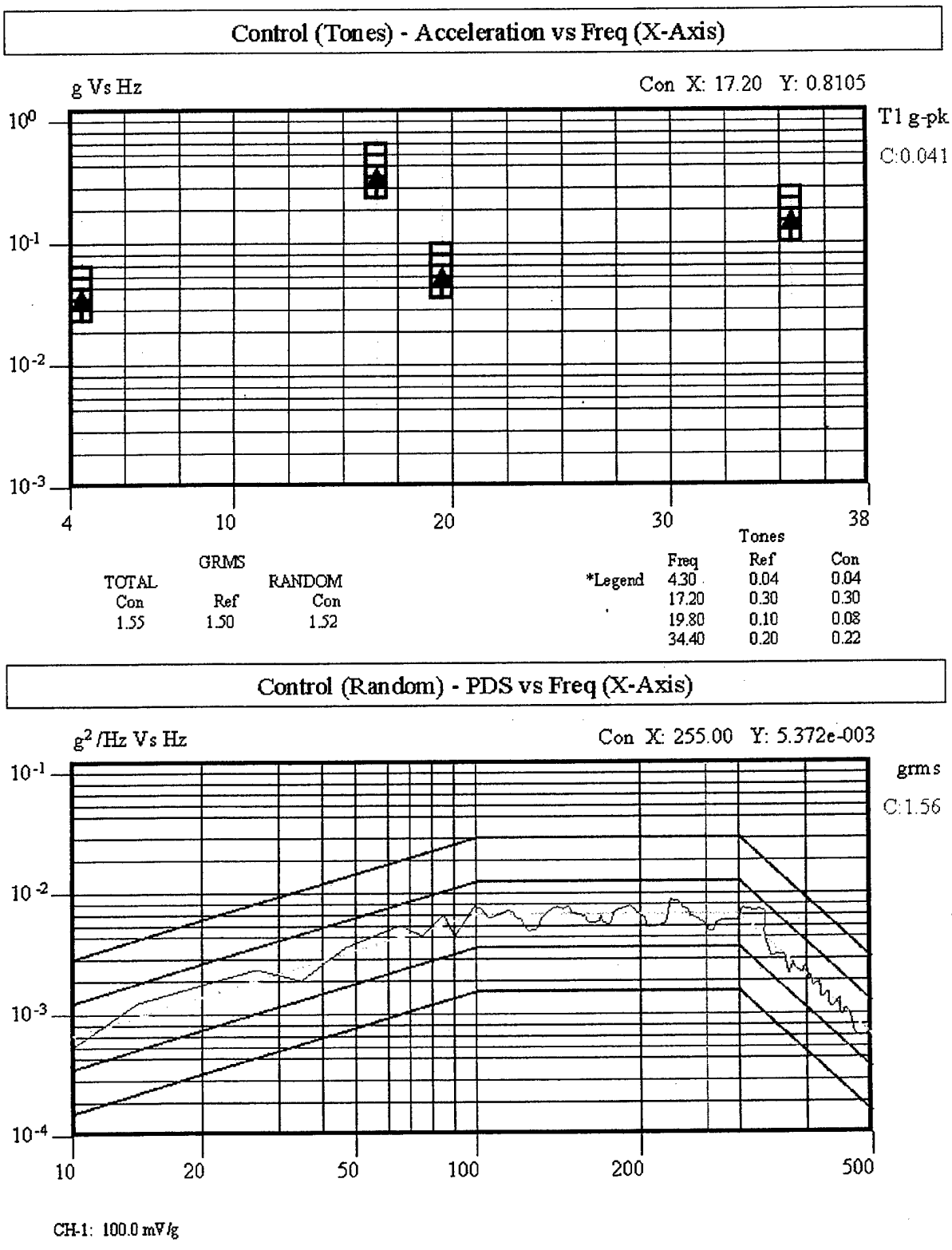

Figure 5. Sine-On-Random X-Axis based on MIL-STD-810E

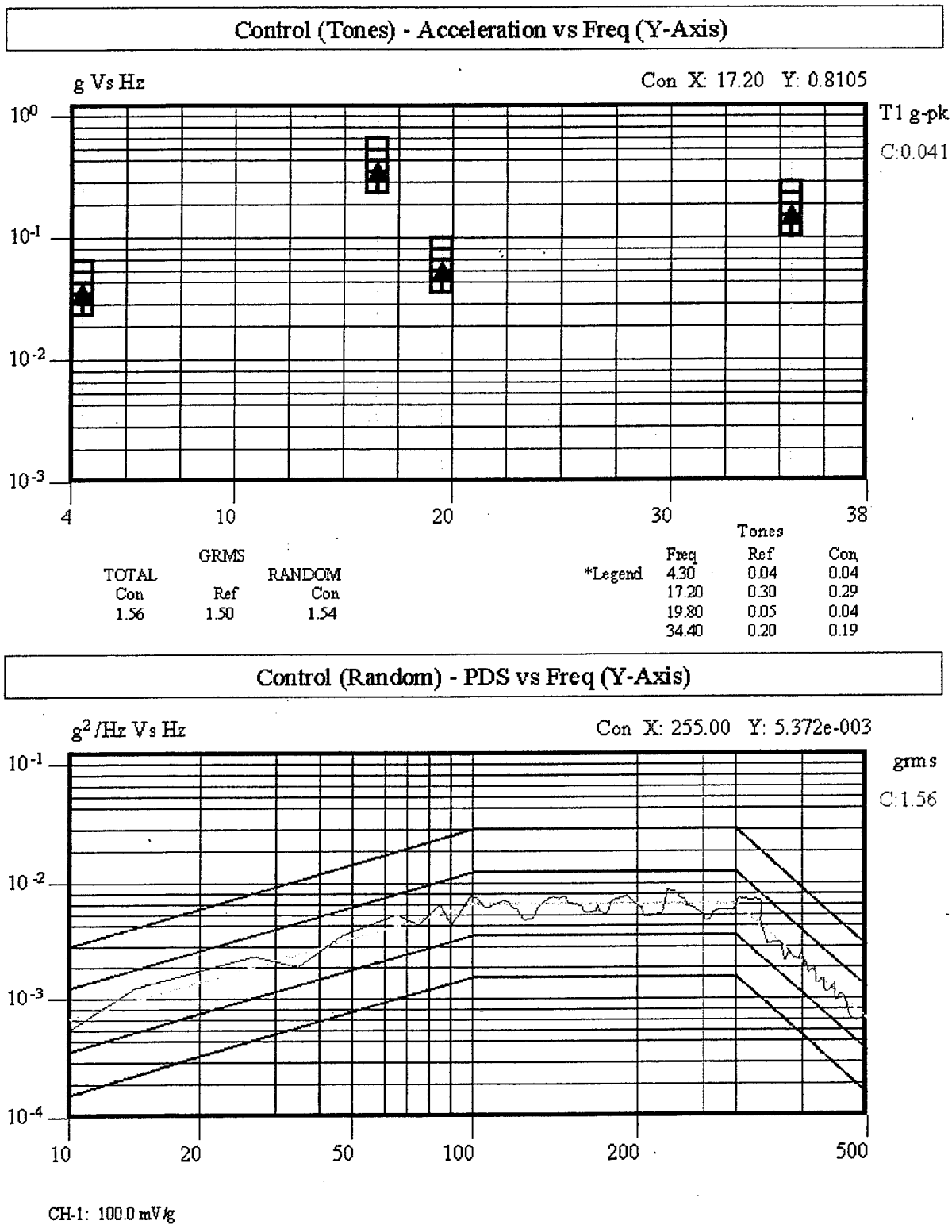

Figure 6. Sine-On-Random Y-Axis based on MIL-STD-810E

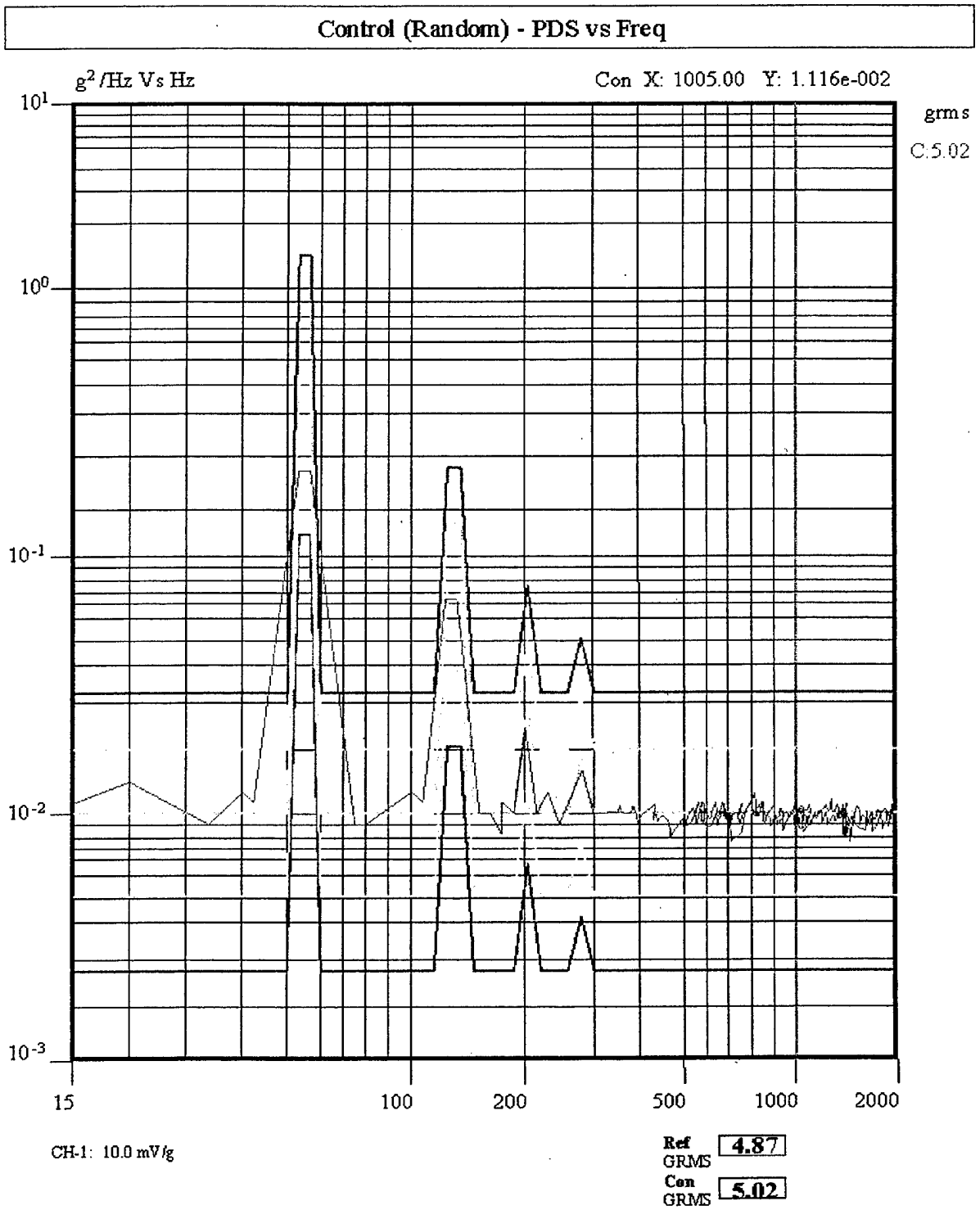

Figure 7. C-130 Turbo-prop based on MIL-STD-810E

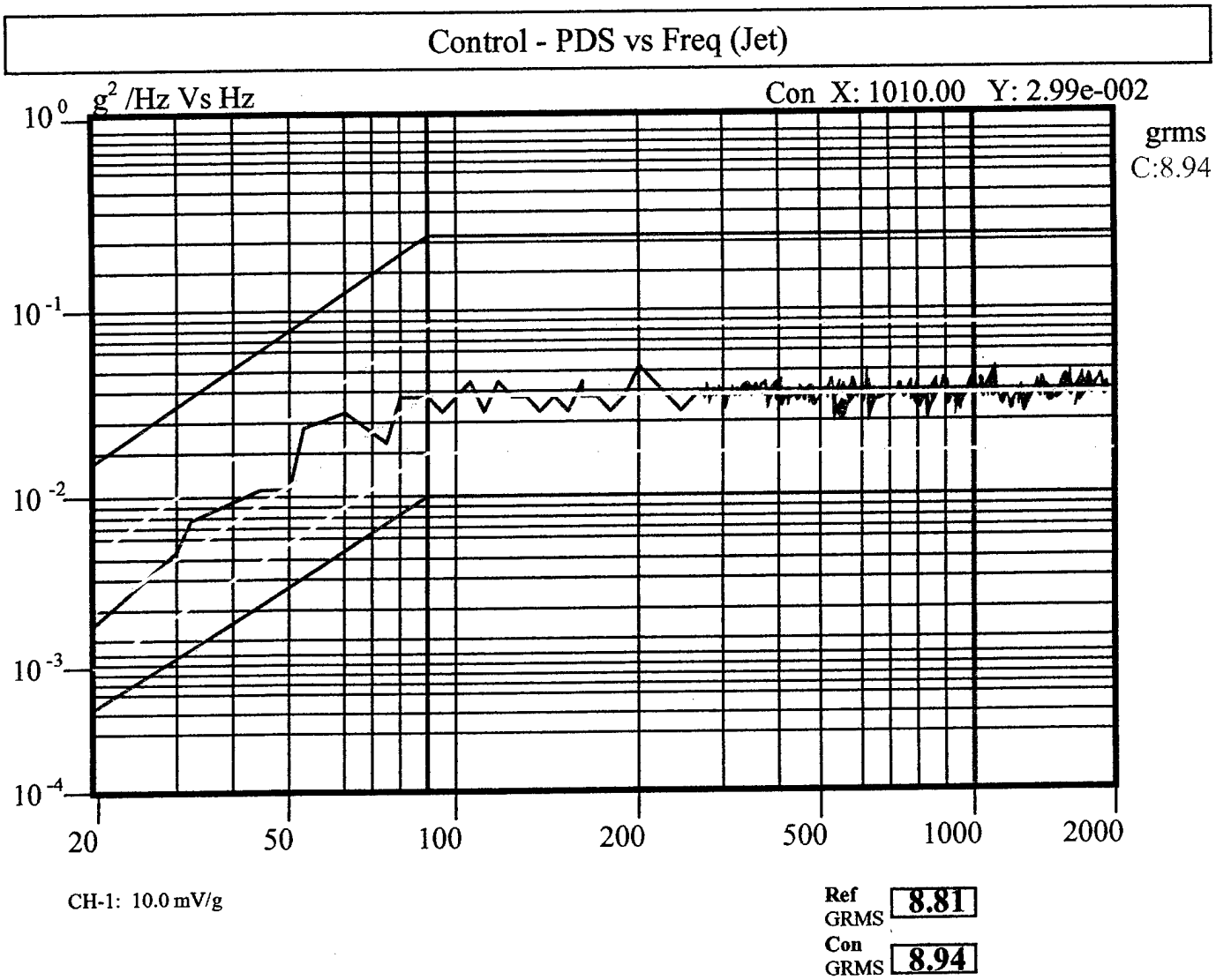

Figure 8. Random Jet based on MIL-STD-810E,

ELECTROMAGNETIC COMPATIBILITY

Electromagnetic compatibility is a primary concern for equipment to be used safely on USAF aeromedical evacuation aircraft. Emissions from medical equipment may cause electromagnetic interference (EMI) with potential influence on aircraft navigation and communications equipment. Medical devices may be susceptible to fields generated by aircraft equipment and malfunction in their presence.

The EUT was evaluated for compliance with MIL-STD 461D & MIL-STD 462D (7 & 8). ASC/ENAI engineers at Wright-Patterson AFB evaluated the electromagnetic compatibility data and determined the airworthiness of the medical device. Specific tests conducted were as follows:

a. Radiated Emissions (RE-102), "Radiated Emissions, Electric Field, 10 kHz to18 GHz.": For Air Force aircraft applications, radiated emissions were measured in a narrower range

of frequencies from 2 MHz - 1 GHz. This test measured the amount of EMI emitted by the EUT during operation. It verifies the EUT's potential to affect other equipment susceptible to electromagnetic emissions (i.e., aircraft navigation and communications equipment).

b. Conducted Emissions (CE-102), "Conducted Emissions, Power Leads, 10 kHz to 10 MHz.": For Air Force aircraft applications, conducted emissions were measured throughout the entire band of 10 kHz - 10 MHz. This test measured emissions generated by the EUT along its power supply lines. It was performed to assess the EUT's potential to affect other items connected to the same power source, particularly aircraft systems.

c. Radiated Susceptibility (RS-103), "Radiated Susceptibility, Electric Field, 10 kHz to 40 GHz.": For Air Force aircraft applications, radiated susceptibility was tested in a narrower frequency range from 30 MHz - 12.4 GHz at the following field strength levels: 20 V/M^2 below 1 GHz and 60 V/M^2 above 1 GHz (MIL-STD-461D field strength values from Table IV, Category Aircraft Internal). This test evaluated the EUT's resistance to predefined levels of EMI generated by antennas both internal and external to the aircraft.

d. Conducted Susceptibility (CS-101), "Conducted Susceptibility, Power Leads, 30 Hz to 50 kHz.": For Air Force aeromedical aircraft applications, conducted susceptibility was tested throughout the entire frequency band, from 30 Hz to 50 kHz. This test evaluated the EUT's ability to "withstand ripple voltages associated with allowable distortion of power source voltage wave forms."

e. Conducted Susceptibility (CS-114), "Conducted Susceptibility, Bulk Cable Injection, 10 kHz to 400 MHz.": For Air Force aeromedical aircraft applications conducted susceptibility was tested throughout the frequency band from 10 kHz to 200 MHz. This test determined whether "simulated currents that will be developed on platform cabling from electromagnetic fields generated by antenna transmission would affect the equipment under test."

f. Conducted Susceptibility (CS-115), "Conducted Susceptibility, Bulk Cable Injection, Impulse Excitation": This test was performed to ensure the EUT could withstand the "fast rise and fall time that may be present due to platform switching operations and external transient environments such as lightning and electromagnetic pulse."

g. Conducted Susceptibility (CS-116), "Conducted Susceptibility, Damped Sinusoidal Transients, Cables and Power Leads, 10 kHz - 100 MHz," respectively. The "basic concept of this test is to simulate electrical current and voltage waveforms occurring in platforms from excitation of natural resonances."

During emissions testing, all the EUT's electrical components/devices were operating for the duration of the test to create worst case emissions scenario. For both emissions and susceptibility testing, the EUT was tested for operation using 115 VAC/60 Hz and 400 Hz and internal battery power.

THERMAL/HUMIDITY ENVIRONMENTAL CONDITIONS

Extreme temperature and humidity testing determines if aeromedical equipment can be stored and operated during severe environmental conditions without experiencing physical damage or deterioration in performance (6). Extreme environmental conditions can have incapacitating effects on medical equipment including the following: changes in material characteristics and material dimensions, overheating, changes in lubricant viscosity, corrosion, changes in electronic components, and electronic or mechanical failures due to rapid water or frost formation.

Due to EUT size and footprint testing was conducted in a large calibrated environmental chamber belonging to the Air Force Research Laboratory, Research Chambers Operation. The EUT was placed in the center of the environmental chamber. All input and output cables and wires were routed through ports in the chamber wall, which were subsequently sealed. The other components of the test setup remained outside the chamber. For operational tests, the EUT was monitored continuously, and a performance check was conducted every 15 minutes. For storage tests, the EUT was placed in the chamber and remained non-operational throughout the storage portion of the test. The following describes the conditions of the environmental tests performed:

a. Humidity: 94 ± 4% RH, 85°F ± 3.6°F (29.5°C ± 2°C) for 4 hr

b. Hot Temp Operation: 120°F ± 3.6°F (49°C ± 2°C) for 2 hr

c. Cold Temp Operation: 32°F ± 7.2°F (0°C ± 4°C) for 2 hr

d. Hot Temp Storage: 140°F ± 3.6°F (60°C ± 2°C) for 6 hr

e. Cold Temp Storage: -40°F ± 3.6°F (-40°C ± 2°C) for 6 hr

HYPOBARIC CONDITIONS

Cabin Pressure/Altitude: Altitude testing is critical for aeromedical evacuation equipment due to potential effects of barometric pressure changes on operation of the equipment. Majority of aircraft, characterized as opportune aircraft, available for use in aeromedical evacuation maintain cabin pressures equivalent to 8,000 - 15,000 ft above sea level. Altitude testing consisted of operating the EUT while ascending from ground level to 15,000 ft, stopping at 2,000 ft increments for performance checks. The rates of ascent and descent were 5,000 ft/min. Testing was conducted in a calibrated man-rated altitude chamber belonging to the Air Force Research Laboratory, Research Chambers Operation.

Rapid Decompression Testing: A rapid decompression (RD) is the loss of aircraft cabin pressurization and subsequent pressure equalization with ambient atmospheric pressure. It is important to assess medical equipment functioning during and after RD so as not to endanger patients, personnel, or the aircraft. The EUT operated inside the rapid decompression test chamber as the chamber was depressurized to an equivalent of 8,000 ft altitude. Then the chamber altitude was brought to 45,000 ft over a period of 60 seconds, held at 45,000 ft for a few

minutes, and then returned to ground at a rate of 10,000 - 12,000 ft/min. The test was repeated twice more, once for a 7-second RD and once for a 1-second RD. The EUT was monitored throughout the series of decompressions. Performance checks were assessed each time the EUT returned to ground level. Testing was conducted in a calibrated man-rated altitude/rapid decompression chamber belonging to the Air Force Research Laboratory, Research Chambers Operation.

AIRBORNE PERFORMANCE

Airborne performance evaluations are a cost-effective and invaluable means of validating clinical and operational suitability of medical equipment items under actual operating conditions. In-flight test and analysis demonstrates the EUT's ability to provide patient care on board USAF aircraft. Safe and reliable operation is the primary goal of the in-flight evaluation and forms the basis for subsequent recommendations to the users.

Flight qualified AFMEDL aeromedical crewmembers flying on C-9 and C-130 aeromedical evacuation missions conducted this phase of testing. The EUT was positioned and secured to an aircraft floor using two 5,000 lbs., cargo tie-down straps and four "D" rings. Then human factor characteristics were evaluated, e.g., securing methods, setup/tear down times and securing locations. Feedback from other aeromedical evacuation crewmembers was obtained concerning EUT human factor considerations.

EXPLOSIVE ATMOSPHERE

The purpose of this test is to demonstrate that operation of the EUT will not ignite a fuel vapor-laden atmosphere.

EVALUATION RESULTS

INITIAL INSPECTION

Initial inspection revealed no manufacturing defects. The unit performed to the manufacturer's specification. Electrical safety test results showed all parameters to be within referenced guideline limits. Battery endurance testing revealed operation time well within manufacturer's specifications. The battery operated the NTS heater and air circulation systems for 3.45 hrs.

VIBRATION

During evaluation, the EUT was secured to the vibration table, using cargo tie down straps with the straps running through the Air/Oxygen cart (see g. under Summary). The EUT experienced some stress fractures in the pull drawer used to house the Impact 326M suction unit (see p. under Summary). The portable air and oxygen bottles experienced scratches and wear

areas where the bottles come in contact with metal housing (see l. under Summary). The rest of the EUT's systems performed according to manufacturer's specifications and AFMEDL guidelines without any system failure or malfunction.

ELECTROMAGNETIC COMPATIBILITY

ASC/ENAI, Wright-Patterson AFB certified the EUT for use the in aeromedical evacuation system on all U.S. Air Force aircraft (including small and large body, fixed and rotary wing) while operating from 115VAC/60 Hz and internal battery power. Numerous changes to the NTS were required and implemented by the manufacturer to achieve successful electromagnetic compatibility. These modifications are discussed in a technical report EMI #99-B12 issued by AFRL/SNZW (11).

THERMAL/HUMIDITY ENVIRONMENTAL CONDITIONS

To meet AFMEDL requirements the EUT must start functioning within 30 minutes following challenges to hot storage (140° F for 6 hours) and cold storage (-40° F for 6 hours). The EUT could not meet these requirements for return to clinical operation. For hot operation (120° F for 2 hours), and cold operation (32° F for 2 hours) the EUT must meet performance requirements under these aster conditions. The EUT could not operate effectively when exposed to these temperatures for prolonged periods. However, the EUT did recover clinical operation once returned to ambient temperature. The EUT did operate in accordance with manufacturer's specifications following modified hot storage (104° F for 6 hours), following modified cold storage (5° F for 6 hours), during modified hot operation (98.6° F for 2 hours), and during modified cold operation (59° F for 2 hours). The major limiting factors were the manufacturer stated temperature limits for the internal battery and the EUT's ability to maintain temperature in the infant chamber. The EUT operated according to AFMEDL and manufacturer's guidelines for humidity. AFMEDL suggests operating the EUT according to manufacturer's specifications and protect the EUT from ambient temperature extremes and direct exposure to sunlight when transporting an infant.

HYPOBARIC CONDITIONS

1. Cabin Pressure/Altitude: The EUT performed in accordance with manufacturer's specifications throughout testing. The unit was able to maintain infant chamber temperature without system failure up to 15,000 ft cabin altitude.

2. Rapid Decompression: The EUT operated satisfactorily following each rapid decompression event. However, the infant mattress was unable to rapidly vent during the rapid pressure changes. Injury to an infant secured inside the infant chamber is very possible due to mattress swelling. To overcome this obstacle, AFMEDL engineer suggests venting the infant mattress to prevent over inflation due to trapped air (see s. under Summary).

AIRBORNE PERFORMANCE

The in-flight evaluation of the EUT was performed on two separate C-9 and C-130 aeromedical evacuation missions. Analysis of performance data indicated this unit was easy to enplane and deplane using two or more crewmembers. The EUT can be plugged directly into Avionics Instruments, Inc., frequency converter or power outlets on the C-9. In certain aircraft such as the C-130/C-141, special training considerations may apply due to aircraft ambient noise affecting audio alarms. The EUT should be positioned to allow visual alarm monitoring throughout all phases of flight. The EUT was secured using two cargo tie-down straps and four "D" rings to secure it to the aircraft floor.

EXPLOSIVE ATMOSPHERE

The EUT was not evaluated for compliance with MIL-STD-810E (6). WRACC/TIECD engineers at Robins AFB, GA have not evaluated the EUT for explosive atmosphere testing. HQ AMC/SGXPL will coordinate future evaluation of this device for use onboard USAF tanker aircraft.

SUMMARY

AFMEDL engineers found the NTS conditionally approved for use during all phases of flight on all USAF aircraft (including small and large body, fixed and rotary wing). The NTS may be used in flight operating on internal battery or powered from 115VAC/60 Hz and 400 Hz aircraft power. However, the Propaq encore 206EL vital signs monitor and Baxter AS50 syringe pumps can only operate from internal batteries or 115VAC/60 Hz power. These devices can not remain plugged into the NTS convenience outlets while the NTS is operating from 115 VAC/400 Hz aircraft power. The NTS underwent extensive internal and external Electromagnetic Interference/Compatibility (EMI) modifications. See below for list of modifications. The NTS could not meet AFMEDL's established requirements for clinical operation following challenges to hot and cold operational testing (120° F for 2 hours and 32° F for 2 hours). However, the NTS did operate according to manufacturer's specifications for ambient environments between 59° F to 98.6° F. Aircrews need to be aware of these ambient operating temperature thresholds and operate the NTS according to manufacturer's guidelines.

The following comments and recommendations apply to this NTS while in the aeromedical evacuation environment:

a. In certain aircraft such as the C-130/C-141, special, training considerations may apply. Consider limitations due to aircraft ambient noise degrading effectiveness of audio alarms. NTS should be positioned to allow continuous visual alarm monitoring by aeromedical crewmembers throughout all phases of flight.

b. On C-9A aeromedical aircraft, the audible cues could be clearly heard and understood within 7 feet of the NTS without the use of hearing protection.

c. Warning labels are required, positioned both inside and outside aluminum access panel door on back of NTS concerning use of 115 VAC/400 Hz power and need to keep panel door closed during flight. 1) "WARNING" USE ONLY 400 HZ COMPATIBLE DEVICES DURING 400 HZ OPERATION. UNPLUG ANY DEVICE THAT CAN NOT SAFELY RUN ON 400 HZ POWER, I.E., PROPAQ ENCORE 206EL VITAL SIGNS MONITOR AND BAXTER AS50 SYRINGE PUMPS. 2) "WARNING" ACCESS PANEL MUST BE KEPT CLOSED DURING INFLIGHT OPERATION.

d. Label the Propaq Encore 206EL's power cable plug-in to allow ease of identification.

e. In keeping with Mil-Std-1472E, all warning, caution and note labels must be written using capital letters. All labels must be positioned to be visible to direct observation and correctly positioned for reading.

f. No transport case/cover was evaluated. Care needs to be taken during transport to prevent NTS damage and protect it from the environment.

g. Securing the NTS to the aircraft floor, AFMEDL requires two standard cargo tie-down straps running across the width of the NTS, through the Air/Oxygen cart between the supports in-back of the wheels. AFMEDL does not recommend using the NTS handle due to limitations on ancillary equipment accessibility and the possibility of handle breakage during ratcheting of the cargo tie-down straps.

h. For securing the NTS in Air Force ambulances, AFMEDL recommends procuring the Retractable Bar Fastener System from International Biomedical, Inc. (P/N: 3170686)

i. During infant transport the NTS requires a minimum of four personnel to load and unload the unit into and from the ambulance, as well as enplaning and deplaning from the aircraft. NOTE: AFMEDL SUGGESTS USING THE LITTER RAMP FOR ENPLANING AND DEPLANING ON C-9A AIRCRAFT AND USE THE CARGO RAMP ON C-17, C-130 AND C-141 AIRCRAFT.

j. Frequent opening of the side door may result in NTS infant chamber over-heating without alarm activation.

k. The Pressed Steel "Q" size tanks must be mounted in the Air/Oxygen cart to prevent regulators and valves from protruding from underneath NTS.

l. To prevent wear and damage to the Pressed Steel "Q" size tanks from the effects of vibration, AFMEDL suggests padding metal areas that come in contact with the Pressed Steel "Q" size tanks, i.e. the retaining bar and the "V" channels the tanks rest on.

m. The mattress in the infant chamber is not vented to relieve excess pressure during a decompression of the aircraft cabin. Suggest the manufacturer place a ¼" diameter vent hole on

mattress ventral surface one inch from mattress edge one at all four corners and one at mid-point. Also suggest using ¼" velcro strip at cover closure. Instead of currently used wider velcro strip.

n. Wheels, located on left side of Air/Oxygen cart as you face the NTS, should be moved 90° outward or round frame corners to prevent possible injury to aeromedical personnel from sharp edges of Air/Oxygen cart frame.

o. Suggest manufacturer provide an opening in the plastic panel above the Air/Oxygen cart or lengthen the AC power cable another 12 inches to allow the NTS's AC power cable better access to 115VAC/60 Hz outlets onboard C-9A aircraft.

p. The pull drawer was an added feature to allow ease of access to the Impact 326M suction device. The drawer reinforcements and the Impact 326M suction securing technique modifications made by International Biomedical, Inc., in response to vibration test data need to be retained.

q. Ensure the Impact 326M and Propaq 206EL's power supplies are mounted in such a way for ease of reading manufacturer and power specifications. i.e., (voltages and amperages).

r. Below is a list of EMI modifications that must be implemented prior to use in flight:

1. EMI filter input power lines.
2. EMI filter the power line to the NTS light at the point where wiring enters the electronics compartment.
3. Place ferrite beads near the circuit card/board to EMI filter signals from the Temperature Probe.
4. EMI shield temperature sensor wire bundle from connector on the control board to temperature sensor ports on Airflow Tray.
5. Ensure the Control panel/display is electrically bonded to the NTS housing.
6. Incorporate a metalized coating to the underside of the Airflow Tray.
7. Enclose electronics compartment with a metal shield to prevent radiated frequencies from entering and escaping the electronics compartment.
8. Place a conductive cover to the apertures on the back side of the NTS where the electrical receptacles are located.

s. To answer a question regarding noise attenuation in the infant chamber, AFMEDL conducted a noise level assessment of the infant chamber during vibration testing. The purpose of the test was to examine whether additional noise inside the infant chamber was generated due to a change in manufacturing design of the plexi-glass hood. The evaluated hood is composed of two separate pieces versus the previous single piece design. The results demonstrated that the new plexi-glass hood does not generate additional environmental noise. Testing showed decreased environmental noise inside the infant chamber when compared to ambient conditions.

t. Baxter AS50 syringe pumps can not be stored above 130° F.

Any public announcement of this Technical Report shall be coordinated between International Biomedical, Inc., this laboratory and the Brooks AFB Public Affairs Office. International Biomedical, Inc., shall not use the name of the Air Force Activity or the Government on any product or service which is directly or indirectly related to this Technical Report. This laboratory or the Government does not directly or indirectly endorse any product or service provided, or to be provided, by International Biomedical, Inc., its successors, assignees, or licensees. International Biomedical, Inc., shall not in any way imply that this Technical Report is an endorsement of any such product or service.

REFERENCES

1. National Fire Protection Agency (NFPA) 99, Health Care Facilities Code
2. Emergency Care Research Institute (ECRI)
3. AFI 41-203, Electrical Shock Hazards
4. AFI 41-201, Equipment Management in Hospitals
5. MIL-STD 1472E, Human Engineering Design Criteria for Military Systems, Equipment, and Facilities.
6. MIL-STD 810E, Environmental Test Methods and Engineering Guidelines.
7. MIL-STD 461D, Electromagnetic Emission and Susceptibility Requirements for the Control of Electromagnetic Interference.
8. MIL-STD-462 D, Measurement of EMI Characteristics.
9. International Biomedical, Inc., Model 20M, Infant Transport Incubator System, Operator's & Service Manual.
10. AFMEDL Procedures Guide, Internal Operating Instruction, Systems Research Branch, Air Force Research Laboratory.
11. AFRL/SNZW Technical Report EMI #99-B12

APPENDIX
MANUFACTURER'S SPECIFICATIONS OF INTERNATIONAL BIOMEDICAL, INC., MODEL 20M, NEONATAL TRANSPORT SYSTEM

SPECIFICATIONS

General

Size:	37.5 in. W. X 30.6 in. H. X 19.2 in. D.
Weight:	175 lbs. with accessory module
Power Requirements:	115 VAC/60 Hz and internal rechargeable battery. 115VAC/400 Hz (NTS and Impact 326 Suction **ONLY**)
Current Draw:	6 amps
Operating time:	Internal batteries: 3 hours of operation @ 37°C ambient temperature. Recharge time 8 hrs on AC, unit off
Environmental	Operating Temperature: (-15°C to 40°C). Humidity: 10 – 95% non-condensing. Pressure: 50 – 106 KPa